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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,905	09/04/2007	Jean-Francois Zagury	ZAGURY8A	5704

1444 7590 10/13/2009

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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
10/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,905	ZAGURY, JEAN-FRANCOIS	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-15,17,18,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-8,10-15,17,18,20 and 21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims 9, 16 and 19 have been canceled as requested in the preliminary amendment filed on 09 April 2009. Following the amendment, claims 1-8, 10-15, 17, 18, 20 and 21 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) **1 (in part)**, 2, **10-15 and 17 (each in part)** drawn to a peptide of SEQ ID NO: 2.

Group II, claim(s) **1 (in part)**, 3, **10-15 and 17 (each in part)**, drawn to a peptide of SEQ ID NO: 5.

Group III, claim(s) **1 (in part)**, 4, **10-15 and 17 (each in part)**, drawn to a peptide of SEQ ID NO: 7.

Group IV, claim(s) **1 (in part)**, 5, **10-15 and 17 (each in part)**, drawn to a peptide of SEQ ID NO: 8.

Group V, claim(s) **1 (in part)**, 6, **10-15 and 17 (each in part)**, drawn to a peptide of SEQ ID NO: 9.

Group VI, claim(s) **1 (in part)**, 7, **10-15 and 17 (each in part)**, drawn to a peptide of SEQ ID NO: 4.

Group VII, claim(s) **1 (in part)**, 8, **10-15 and 17 (each in part)**, drawn to a peptide of SEQ ID NO: 10.

Group VIII, claim(s) **18 (in part)**, drawn to an antibody specific to a peptide of SEQ ID NO: 2.

Group IX, claim(s) **18 (in part)**, drawn to an antibody specific to a peptide of SEQ ID NO: 5.

Group X, claim(s) **18 (in part)**, drawn to an antibody specific to a peptide of SEQ ID NO: 7.

Group XI, claim(s) **18 (in part)**, drawn to an antibody specific to a peptide of SEQ ID NO: 8.

Group XII, claim(s) **18 (in part)**, drawn to an antibody specific to a peptide of SEQ ID NO: 9.

Group XIII, claim(s) **18 (in part)**, drawn to an antibody specific to a peptide of SEQ ID NO: 4.

Group XIV, claim(s) **18 (in part)**, drawn to an antibody specific to a peptide of SEQ ID NO: 10.

Group XV, claim(s) **20 (in part)**, drawn to a method for treatment of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of an antibody specific to a peptide of SEQ ID NO: 2.

Group XVI, claim(s) **20 (in part)**, drawn to a method for treatment of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of an antibody specific to a peptide of SEQ ID NO: 5.

Group XVII, claim(s) **20 (in part)**, drawn to a method for treatment of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of an antibody specific to a peptide of SEQ ID NO: 7.

Group XVIII, claim(s) **20 (in part)**, drawn to a method for treatment of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of an antibody specific to a peptide of SEQ ID NO: 8.

Group XIX, claim(s) **20 (in part)**, drawn to a method for treatment of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of an antibody specific to a peptide of SEQ ID NO: 9.

Group XX, claim(s) **20 (in part)**, drawn to a method for treatment of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of an antibody specific to a peptide of SEQ ID NO: 4.

Group XXI, claim(s) **20 (in part)**, drawn to a method for treatment of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of an antibody specific to a peptide of SEQ ID NO: 10.

Group XXII, claim(s) **21 (in part)**, drawn to a method for treatment or prevention of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of a peptide of SEQ ID NO: 2.

Group XXIII, claim(s) **21 (in part)**, drawn to a method for treatment or prevention of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of a peptide of SEQ ID NO: 5.

Group XXIV, claim(s) **21 (in part)**, drawn to a method for treatment or prevention of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of a peptide of SEQ ID NO: 7.

Group XXV, claim(s) **21 (in part)**, drawn to a method for treatment or prevention of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of a peptide of SEQ ID NO: 8.

Group XXVI, claim(s) **21 (in part)**, drawn to a method for treatment or prevention of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of a peptide of SEQ ID NO: 9.

Group XXVII, claim(s) **21 (in part)**, drawn to a method for treatment or prevention of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of a peptide of SEQ ID NO: 4.

Group XXVIII, claim(s) **21 (in part)**, drawn to a method for treatment or prevention of a disease associated with the pathogenic overproduction of ILβ or TNFα, comprising administration of a peptide of SEQ ID NO: 10.

It is noted that most of the claims encompass subject matter that spans several inventions (set forth in bold above). When applicant elects an invention, said claims will only be examined to the extent that they read on the elected invention (see PCT Rule 13.3, Determination of Unity of Invention Not Affected by Manner of Claiming, which states that the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard

to whether the inventions are claimed in separate claims or as alternatives within a single claim).

The inventions listed as Groups I-XXVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XXVIII is that they all relate to a peptide homologous to one of SEQ ID NOs: 2, 5, 7, 8, 9, 4 and 10, and a method for treatment comprising administration of said peptide. However, Zagury (WO 03084979, published 16 October 2003, cited on IDS dated 08 June 2009) teaches a peptide that is 100% identical to SEQ ID NO: 2 and methods of treating diseases characterized by an overproduction of cytokines, comprising administration of the peptide (see sequence alignment, which includes the abstract of the WO document, below). Thus, the technical feature linking the inventions of Groups I-XXVIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

```
SEQ ID NO: 2
RESULT 1
ADK41080
ID   ADK41080 standard; peptide; 16 AA.
XX
AC   ADK41080;
XX
DT   06-MAY-2004  (first entry)
XX
DE   Human tumor necrosis factor alpha derived peptide #2.
XX
KW   immunosuppressive; neuroprotective; antirheumatic; antiarthritic;
KW   antipsoriatic; antidiabetic; dermatological; antiinflammatory;
KW   antiallergic; antiasthmatic; cytostatic; anti-HIV; vaccine; cytokine;
KW   multiple sclerosis; rheumatoid polyarthritis; psoriasis;
KW   autoimmune diabetes; lupus; allergy; asthma; cancer; AIDS;
KW   immune response.
XX
OS   Homo sapiens.
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XX
PN   WO2003084979-A2.
XX
PD   16-OCT-2003.
XX
PF   09-APR-2003; 2003WO-FR001120.
XX
PR   10-APR-2002; 2002FR-00004464.
XX
PA   (ZAGU/) ZAGURY J.
XX
PI   Zagury J;
XX
DR   WPI; 2003-812717/76.
XX
PT   New cytokine-derived peptide, useful as vaccine for treating conditions
PT   caused by excess cytokine, contains residues closely associated with a
PT   cytokine receptor.
XX
PS   Claim 8; SEQ ID NO 6; 42pp; French.
XX
CC   The invention relates to novel peptides (I) of 5-40 amino acids (aa)
CC   derived from a cytokine in which at least one aa has at least one of its
CC   atoms spaced a distance (d), evaluated from structural data, less than 5
CC   angstrom from an atom of the corresponding cytokine receptor is new.
CC   Excluded are peptides from between the 2nd and 3rd Cys of RANTES and from
CC   residues 123-140 of interferon-alpha. (I) and their derivatives, also
CC   peptides from the 123-140 region of interferon-alpha, are useful for
CC   treatment and prevention of diseases associated with high levels of
CC   cytokines, e.g. multiple sclerosis, rheumatoid polyarthritis, psoriasis,
CC   autoimmune diabetes, lupus, allergy, asthma, cancer and AIDS. Since (I)
CC   correspond to regions very close to the receptor, production of
CC   antibodies that facilitate or potentiate cytokines is limited, and the
CC   quality of the immune response is improved by restricting the number of
CC   antigenic determinants targeted. This sequence corresponds to a peptide
CC   of the invention.
XX
SQ   Sequence 16 AA;

  Query Match             100.0%;  Score 73;  DB 1;  Length 16;
  Best Local Similarity   100.0%;
  Matches   16;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 ISRIAVSYQTKVNLLS 16
              ||||||||||||||||
Db          1 ISRIAVSYQTKVNLLS 16
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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached at (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G.E./
Gregory S. Emch
Patent Examiner
Art Unit 1649
07 October 2009

/Daniel E. Kolker/
Primary Examiner, Art Unit 1649
October 8, 2009